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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUH, BENJAMIN	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,734	HUNTER ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/10/06.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5-10, 20, & 28-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Nason et al (US Patent No. 6375638 B2). Nason et al discloses a medication delivery device in figures 1-8 with a chamber 112 for holding a drug to be injected into a biological body; a nozzle 116 in fluid combination with the chamber 112, the drug being injected through the nozzle; a piston 108 positioned in the chamber 112; and an actuator 10 coupled to the piston 108; the actuator 10 including a member 30 that contracts when a potential is applied to the member, the actuator moving the piston towards the nozzle when the electrical potential is applied to the member to expel the drug out of the chamber through the nozzle as can be seen in figure 3, wherein the member is seen to be extending substantially along the length of the piston, an inlet port for filling the chamber with the drug would be through the removal of the piston 108 and filling the chamber 112 with more drug. The medication delivery device is also inherently capable of being configured to inject a drug to a depth beneath an animal's skin due to

its size, shape and ability to work in the environment since it is stated in col. 6 lines 12-15 that it "may be configured to attach to catheters, needles, luers, infusion sets or the like".

With regards to claims 5-10, the member 30 mentioned above can be a wire made of nickel-titanium alloy which is a shape memory material/polymer and the shape memory alloy structure changes phase from martensite to austenite, attention is directed to col. 5 lines 32-55.

With regards to claim 20, Nason et al discloses in figure 3 and in the specification a drug held in chamber 112 which is in fluid communication with a nozzle 116; applying a potential to a member 30 of an actuator 10, the member contracting upon the application of the potential, the actuator being coupled to a piston 108, the actuator moving the piston towards the nozzle when the potential is applied to the member col. 5 lines 56-65, and expelling the drug from the chamber through the nozzle as the piston moves towards the chamber.

With regards to claims 28-33, for providing a shaped memory material alloy specifically nickel-titanium attention is directed to col. 5 lines 32-55.

Claims 1-2, 5-11, 17, 20, & 28-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Beaumont et al (US Pub. No. 20050022806 A1). Beaumont et al discloses a medication delivery device in figures 2a-c with a chamber 120 for holding a drug to be injected into a biological body; a nozzle 114 in fluid combination with the chamber 120, the drug being injected through the nozzle; a piston 122 positioned in the

chamber 120; and an actuator 130 coupled to the piston 122; the actuator 130 including a member 150 that contracts when a potential is applied to the member, the actuator moving the piston towards the nozzle when the electrical potential is applied to the member to expel the drug out of the chamber through the nozzle as can be seen in figures 2b-c, wherein the member is seen to be extending substantially along the length of the piston, also see para [0245] – [0247].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 17-18, 20-23, & 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable by Venditty et al (US Patent No. 2928390) in view of Beaumont et al (US Pub. No. 20050022806 A1) or Flaherty (US Patent no. 6656159B2 & 6723072 B2). Venditty et al discloses a multi-dose hypodermic injector seen in figures 1-13 comprising a chamber 25 for holding a drug to be injected into a biological body; a nozzle 24a in fluid communication with the chamber 25, the drug being injected through the nozzle 24a; a piston 22 positioned within the chamber 25; and an actuator seen as a combination of elements in figures 1-3 coupled to the piston 22, the actuator including a member 98 that contracts when a potential is applied to the member in which the

potential placed on the spring causes it to compress/contract, the actuator moving the piston towards the nozzle when the potential is applied to the a member to expel the drug out of the chamber through the nozzle see col. 8 line 69 to col. 9 line 59, thereby delivering the drug to a depth beneath an animal's skin. Now even though Venditty does not explicitly disclose an actuator that utilizes a member that contracts when an electrical potential is applied to the member with the member extending substantially along the length of the piston, attention is directed to Beaumont or Flaherty. The Beaumont reference teaches the use of a shape memory alloy member 150 that contracts to actuate a piston, see para [0245]-[0247]. The Flaherty references teach the use of shape memory materials in which the shape memory alloy/polymer changes phase from martensite to austenite, more specifically a nickel-titanium alloy in wire form see in '159 col. 11 lines 11 – 38. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Venditty with the teachings of Beaumont or Flaherty in order to provide a function equivalent for injecting the drug or to provide a sturdy actuator with a consistent ability to replicate a specific amount of contraction.

With regards to claims 2 & 11, the injector further comprises an inlet port 43 from a reservoir 44 for filling the chamber with the drug.

With regards to claims 3 & 4, the resilient member which is a coiled spring 79 applies a force to the piston away from the nozzle.

With regards to claims 5-10 & 28-33, see Beaumont para [0047] – [0058].

With regards to claims 18, 21, & 35, even though Venditty in view of Flaherty does not explicitly state that the drug is expelled through the nozzle with an injection velocity of at least about 100 meters per second it is deemed that the device would be inherently capable of expelling at drug at 100 m/s since it has an equivalent structure and would therefore function in an equivalent matter. Also, it is believed that it would be obvious to one of ordinary skill in the art at the time of the invention to adjust the parameters of the injection device in order to achieve whichever injection velocity is desired.

With regards to claim 20, the method of injecting a drug into a biological body is disclosed comprising holding a drug in a chamber 25, the chamber being in fluid communication with a nozzle 24a through which the drug is injected; applying a potential to a member 98 of an actuator seen as various components in figures 1-3, the member contracting upon the application of the potential, the actuator being coupled to a piston, the actuator moving the piston towards the nozzle when the potential is applied to the member; and expelling the drug from the chamber through the nozzle as the piston moves towards the chamber (see col. 8 line 69 to col. 9 line 59).

With regards to claim 22, the piston moving away from the nozzle with a spring when the potential is removed from the actuator is achieved through spring 79 which retracts the piston after the injection.

With regards to claim 23, the injector further comprises a reservoir 44 coupled to the chamber 25 for supplying the drug.

Claims 12 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venditty et al (US Patent No. 2928390) in view of Beaumont et al (US Pub. No. 20050022806 A1) or Flaherty (US Patent no. 6656159B2 & 6723072 B2) as applied above and further in view of Smoliarov et al (US Patent No. 6626871B1). Even though Venditty does not disclose a sterile interface positioned between the nozzle and the body attention is directed to Smoliarov. Smoliarov discloses a medical device which utilizes a sterile interface 30 positioned in front of the nozzle so that it would be between the nozzle and the body as seen in figure 4. Therefore, it would be obvious to one of ordinary skill in the art to incorporate the sterile interface of Smoliarov into the device of Venditty in order to keep the device sterile and clean and to help prevent the spread of infection.

Claims 13 & 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venditty et al (US Patent No. 2928390) in view of Beaumont et al (US Pub. No. 20050022806 A1) or Flaherty (US Patent no. 6656159B2 & 6723072 B2) as applied above and further in view of Smoliarov et al (US Patent No. 6626871B1) in further view of Henderson (US Patent No. 3574431) or Gaide et al (US Pub No. 2002/0145364A1). Even though Venditty in view of Smoliarov does not disclose a flexible ribbon supplied from a roller, a new sterile position of the ribbon attention is directed to Henderson and Gaide which both disclose "flexible ribbon" supplied from a roller and are inherently capable of being positioned over the nozzle of an injector due to its size, shape and ability to work in the environment and would therefore be obvious to one of ordinary skill

in the art at the time of the invention to utilize rollers to provide new sterile ribbon in order to keep the injector clean and the subjects from infection.

Claims 14-15 & 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venditty et al (US Patent No. 2928390) in view of Beaumont et al (US Pub. No. 20050022806 A1) or Flaherty (US Patent no. 6656159B2 & 6723072 B2) as applied above and further in view of D'Antonio (US Patent No. 5318522). Even though Venditty does not utilize a plurality of vials which can be sequentially supplied to the injector, a new vial being positioned in the injector after an injection attention is directed to D'Antonio. D'Antonio discloses a hypodermic fluid dispenser with a plurality of vials placed in a collapsible cartridge magazine which can sequentially supply the vials to the injector. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize a sequential vial cartridge system as in D'Antonio into the device and method of Venditty in order to separate the drugs into different containers and to be able to have set amounts of the drug prepared for delivery.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venditty et al (US Patent No. 2928390) in view of Beaumont et al (US Pub. No. 20050022806 A1) or Flaherty (US Patent no. 6656159B2 & 6723072 B2) as applied above and further in view of Hagen (US Patent No. 5354273). Even though Venditty does not disclose a skin sensor and a servo-controller to adjust the injection pressure of the injector with respect to the skin properties attention is directed to Hagen. Hagen discloses a delivery

apparatus with pressure controlled delivery utilizing a skin sensor 23 and a servo-controller (34,36) which adjusts the injection pressure of the drug injector with respect to the skin properties. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the skin sensor & servo-controller of Hagen into the device of Venditty in order to better cater the pressure and use of the device to each individual subject.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venditty et al (US Patent No. 2928390) in view of Beaumont et al (US Pub. No. 20050022806 A1) or Flaherty (US Patent no. 6656159B2 & 6723072 B2) as applied above and further view of Hagen (US Patent No. 5354273). For this claim the elements will be referenced differently in which the drug injector comprises a housing seen to encompass the entire device of Venditty, a vial 44 which holds the drug to be injected, a nozzle 24a, a piston 22 positioned within the housing; and an actuator seen as a combination of elements coupled to the piston. Even though Venditty does not disclose the actuator including a member that is a material of shape memory materials attention is directed to Flaherty. The Flaherty references teach the use of shape memory materials in which the shape memory alloy/polymer changes phase from martensite to austenite, more specifically a nickel-titanium alloy in wire form see in '159 col. 11 lines 11 – 38, is used as an actuator therefore it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the shape memory materials actuator of Flaherty in the device and method of

Venditty in order to provide a consistent, cheap, and reliable method of injecting a substance. Also, even though Venditty in view of Flaherty does not disclose a skin sensor and servo-controller attention is now directed to Hagen. Hagen discloses a delivery apparatus with pressure controlled delivery utilizing a skin sensor 23 and a servo-controller (34,36) which adjusts the injection pressure of the drug injector with respect to the skin properties. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the skin sensor & servo-controller of Hagen into the device of Venditty in order to better cater the pressure and use of the device to each individual subject.

Response to Arguments

Applicant's arguments filed 7/10/06 have been fully considered but they are not persuasive.

The applicant argues that Nason does not disclose a member that contracts when an electrical potential is applied to the member and that the member does not extend substantially along the length of the piston, the examiner disagrees. The Nason reference does indeed utilize an electrical potential in order to contract the shape memory allow member in order to move the piston. Also, wherein the member is seen to extend substantially along the length of the piston since the term "substantially" is not explicitly defined in the specification as to approximate what length, therefore it is the examiner's position that the member does indeed extend substantially along the length of the piston when the member is adjacent the piston.

Applicant's arguments with respect to the rest of the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mulhauser et al (US Patent No. 5919167) discloses the use of an actuator with shape memory alloy members see col. 3 lines 26-58. Smolyarov et al (US Patent No. 6770054B1) & Smoliarov et al (US Patent No. 6626871) also disclose the use of a driving means utilizing a nickel-titanium alloy which contracts as well as sterile interfaces in the front caps. Scherer (US Patent No. 2754818) also discloses an injection device. D'Antonio et al (US Patent No. 6056716) also discloses an injector with sequential vial delivery possibilities.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons